



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 23 2007

Re: Infuse Bone Graft / LT Cage Lumbar Tapered Fusion
Docket No. 2003E-0243
Docket No. 2003E-0244

Food and Drug Administration
Rockville MD 20857

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the patent term extension applications for U.S. Patent Nos. 5,782,919 and 5,984,967 filed by SDGI Holdings, Inc. under 35 U.S.C. § 156. The patents claim the product, Infuse Bone Graft/LT Cage Lumbar Tapered Fusion, PMA P000058.

In the March 28, 2007, issue of the Federal Register (72 Fed. Reg. 14582), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before September 24, 2007, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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